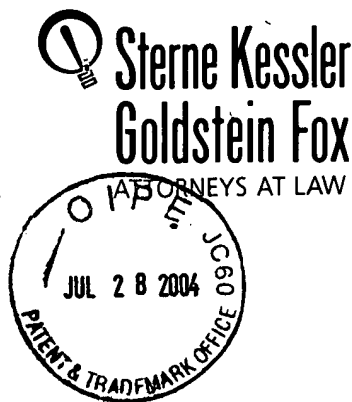


AF/1644 IFW



Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Esmond
Tracy-Gene G. Durkin
Michele A. Cimbala
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Millonig
Donald J. Featherstone
Lawrence B. Bugaisky
Michael V. Messinger

Judith U. Kim
Timothy J. Shea, Jr.
Patrick E. Garrett
Heidi L. Kraus
Edward W. Yee
Albert L. Ferro
Donald R. Banowitz
Peter A. Jackman
Teresa U. Medler
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Eldora Ellison Floyd
Thomas C. Fiala
Brian J. Del Buono
Virgil Lee Beaton
Kimberly N. Reddick
Theodore A. Wood

Elizabeth J. Haanes
Joseph S. Ostroff
Frank R. Cottingham
Christine M. Lhulier
Rae Lynn Prengaman
Jane Shershenovich
George S. Bardmesser
Daniel A. Klein
Jason D. Eisenberg
Michael D. Specht
Andrea J. Kamage
Tracy L. Muller
LuAnne M. DeSantis
John J. Figueroa
Ann E. Summerfield
Tiera S. Coston
Aric W. Ledford
Jessica L. Parezo

Timothy A. Doyle
Gaby L. Longworth
Nicole D. Dretar
Ted J. Ebersole
Jyoti C. Iyer
Registered Patent Agents
Karen R. Markowicz
Nancy J. Leith
Helene C. Carlson
Matthew J. Dowd
Aaron L. Schwartz
Katrina Y. Pei Quach
Bryan L. Skelton
Robert A. Schwartzman
Teresa A. Colella
Jeffrey S. Lundgren
Victoria S. Rutherford

Eric D. Hayes
Michelle K. Holoubek
Robert H. DeSels
Simon J. Elliott
Julie A. Heider
Mita Mukherjee
Scott M. Woodhouse

Of Counsel
Kenneth C. Bass III
Evan R. Smith
Marvin C. Guthrie

*Admitted only in Maryland
*Admitted only in Virginia
•Practice limited to
Federal Agencies

July 28, 2004

WRITER'S DIRECT NUMBER:
(202) 772-8543
INTERNET ADDRESS:
AKAMAGE@SKGF.COM

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1644

Re: U.S. Utility Patent Application
Application No. 09/833,203; Filed: April 12, 2001
For: **Targeted Vaccine Delivery Systems**
Inventors: ZAUDERER *et al.*
Our Ref: 1821.0020001/EKS/AJK

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fee Transmittal Form (PTO/SB/17);
2. PTO-2038 Credit Card Payment Form;
3. Reply Under 37 C.F.R. § 1.116;
4. Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences - Small Entity; and
5. Return postcard.

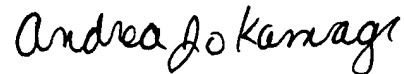
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
July 28, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Andrea Jo Kamage
Agent for Applicants
Registration No. 43,703

EKS/AJK/jk
Enclosures

293044



**Amendment Under 37 C.F.R. § 1.116
Expedited Procedure – Art Unit 1644**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Zauderer *et al.*

Appl. No.: 09/833,203

Filed: April 12, 2001

For: **Targeted Vaccine Delivery Systems**

Confirmation No.: 1700

Art Unit: 1644

Examiner: Vandervegt, Francois P.

Atty. Docket: 1821.0020001/EKS/AJK

Reply Under 37 C.F.R. § 1.116

Mail Stop AF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated April 28, 2004, Applicants submit the following Amendment and Remarks. This Amendment is provided in the following format:

- (A) Each section begins on a separate sheet; and
- (B) Starting on a separate sheet, the Remarks.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Remarks

Reconsideration of this Application is respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 27, 31, 36, 39, 120, 124, 128 and 130 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Savage, WO 99/64464 (hereinafter "Savage"); in view of Cormier *et al.*, *Int. J. Cancer* 75:517-524 (1998) (hereinafter "Cormier"); Schnell *et al.*, *J. Immunol.* 164:1243-1250 (2000) (hereinafter "Schnell"); and Zarour *et al.*, *Proc. Natl. Acad. Sci. USA* 97:400-405 (2000) (hereinafter "Zarour"). Applicants respectfully traverse this rejection.

The Office Action stated that

[g]iven the level of skill attributable to the person of ordinary skill in the art at the time the invention was made, the artisan would have understood that engineering MHC class II molecules to bind to the same cancer cells as MHC class I and provide support for the cytotoxic response (Savage) would have provided a reasonable expectation that the normally low response to MelanA/MART-1 (Cormier), generating a more robust response (Schnell) to the same antigen (Zarour).

April 28, 2004 Office Action, p. 4.

This statement, however, does not refer to any suggestion or motivation found within the references to modify or combine the reference teachings. Furthermore, this statement is not an explanation as to why the skilled artisan would modify the disclosure of Savage to arrive at Applicants' claimed invention. Rather, the Examiner's statement

merely lists the alleged teachings of each of these references. Absent a motivation or suggestion to combine reference teachings, the examiner has improperly relied upon hindsight reasoning in combining references in support of the rejection under 35 U.S.C. § 103(a). *Cf.* M.P.E.P. §§ 2142 and 2143 (rev. 8th ed. Feb. 2003).

Even if there were a proper suggestion or motivation for combining these four references to arrive at an MHC class II / antibody complex, any combined teachings could not satisfy the criteria for setting forth a *prima facie* case of obviousness with respect to the presently examined claims. Among other limitations, none of the references teach or suggest combining an antibody specific for a cell surface marker of a colon cancer cell with an antigenic peptide derived from a melanoma cell.

Savage teaches an MHC class I - antibody complex, but does not teach the melanoma antigen of the claims. Schnell only discloses that MHC class II helper T cells can enhance the MHC class I cytotoxic response. Zarour and Cormier teach a melanoma antigen, but they neither teach nor suggest that a melanoma antigen can be used to upregulate an immune response to colon cancer cells.

The Examiner has not pointed out where in the references it is taught that an MHC complex which includes an antigen derived from melanoma cells should be linked to an antibody specific for colon cancer cells. The skilled artisan would not have a reasonable expectation of success based on the cited art because none of the art relied upon by the Examiner teaches or suggests that an antigen for one type of cancer (melanoma) can be used to upregulate the immune response to another type of cancer (colon).

Accordingly, a *prima facie* case of obviousness has not been established. Withdrawal of this rejection is respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Andrea Jo Kamage

Andrea Jo Kamage
Agent for Applicants
Registration No. 43,703

Date: 7/28/04

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

283102